

In the Claims

1. (Currently Amended) A method for detecting contaminating microbes possibly present in a blood product comprising blood cells comprising:

a) providing a sterile device for concentrating microbes possibly present in a blood product containing blood cells comprising

a first watertight, sterile tank containing a piston and at least one blood cell aggregation agent and, optionally, at least one marker agent for labeling pathogenic microbes;

a second watertight, sterile tank containing at least one lysis agent for blood cells and, optionally, at least one marker agent for labeling pathogenic microbes;

a first filter located between the first tank and the second tank and having pores;

a second filter enclosed in a membrane support having two removable, separable parts and located downstream of the second tank and having pores;

a first watertight, sterile connector joining the first tank and the first filter;

a second watertight, sterile connector joining the first filter and the second tank;

a third watertight, sterile connector joining the second tank and the second filter;

a fourth watertight, sterile connector comprising a reverse lock valve and joining a bag containing a blood product to the first sterile tank.

b) subjecting a sample of the blood product to an aggregation treatment of the blood cells in the first tank,

b) c) substantially eliminating aggregates formed in step (a) (b) by passage of the sample over [[a]] the first filter allowing to allow passage of contaminating microbes, but not cell aggregates,

e) d) selectively lysing residual cells of the filtrate obtained in step (b) (c) in the second tank,

d) e) adding a marker agent to label labeling the contaminating microbes with a marker agent either during step (a) (b) or step (e) (d),

e) f) recovering the contaminating microbes by passage of the lysate from step (e) (d) over [[a]] the second filter with a pore size of about 0.3 μm to less than 1 μm which retains to retain contaminating microbes and allows allow passage of cellular debris, and

f) g) analyzing material on the second filter to detect labeled contaminating microbes possibly retained by the second filter,

said method being performed in ~~an enclosed and~~ the sterile device.

2. (Currently Amended) The method according to claim 1, further comprising ~~addition of~~ adding a permeabilization agent of the contaminating microbes in the first tank or second tank in at least one of the steps ~~(a), (e) or (e)~~ (b), (d) or (f).

3. (Previously Presented) The method according to claim 2, wherein the permeabilization agent is selected from the group consisting of polyethylene imine, chlorhexidine diacetate, chlorhexidine digluconate, ethylene diamine tetraacetate acid (EDTA) alone or in combination with nisin, a detergent and mixtures thereof.

4. (Previously Presented) The method according to claim 3, wherein the detergent is selected from the group consisting of N-octyl β -D-glucopyranoside, SDS, polyoxyethyleneglycol dodecyl ether and mixtures thereof.

5. (Original) The method according to claim 1, wherein the marker agent is a marker solution selected from among the group consisting of an esterase substrate, a labeled antibody and a marker of nucleic acids.

6. (Original) The method according to claim 1, wherein the marker agent comprises a fluorescent marker or an agent coupled to a fluorochrome or an enzyme enabling degradation of a substrate thereby made fluorescent.

7. (Previously Presented) The method according to claim 6, wherein fluorescence is produced using an excitation laser and detected.

8. (Original) The method according to claim 1, wherein the blood cells of the blood product are platelets or red cells or a mixture thereof.

9. (Currently Amended) The method according to claim 1, wherein the blood product comprises platelets and step ~~(a)~~ (b) comprises bringing the sample into contact with an aggregation composition comprising at least one aggregation agent selected from the group consisting of 1) a specific antibody of a platelet antigen, 2) a strong agonist of platelet activation selected from the group consisting of thrombin, TRAP (thrombin receptor activating peptide), trypsin, collagen, thromboxane A2, PAF (platelet activating factor), ionophore A23187, immune complexes and complement factors, and 3) a weak agonist of platelet activation selected from the group consisting of ADP, adrenalin, arachidonic acid, Von Willebrand factor, serotonin and epinephrine.

10. (Original) The method according to claim 9, wherein concentration of the antibody is between about 0.5 µg/ml and about 50 µg/ml.

11.-12. (Cancelled)

13. (Original) The method according to claim 9, wherein the antibody is selected from the group consisting of an anti-CD, anti-CD32, anti-PTA1, anti-D42, anti-GpIIb/IIIa and anti-GpIV antibody.

14. (Currently Amended) The method according to claim 1, wherein the blood product comprises red cells and step ~~(a)~~ (b) comprises bringing the sample into contact with an agglutination composition comprising at least one agglutination agent selected from the group consisting of lectins, polyethylene imine, polyvinylpyrrolidone (PVP), gelatins, dextrans and polyethylene glycols (PEG).

15. (Original) The method according to claim 14, wherein the lectins have erythroagglutinin activity.

16. (Original) The method according to claim 14, wherein the lectins are selected from the group consisting of *Phaseolus vulgaris*, *Vicia sativa*, *Vicia faba* and *Erythrina corallodendron*.

17. (Original) The method according to claim 16, wherein concentration of *Phaseolus vulgaris* lectin is between about 10 µg/ml and about 200 µg/ml.

18.-22. (Cancelled)

23. (Currently Amended) The method according to claim 1, wherein step ~~(e)~~ (d) is performed with a lysis solution comprising one or more detergents selected from the group consisting of saponin, SDS, polyoxyethyleneglycol dodecyl ether, Polidocanol, N-octyl β-D-glucopyranoside and sodium carbonate.

24. (Original) The method according to claim 1, wherein the contaminating microbes are aerobic or anaerobic bacteria, molds, yeasts, or live and/or dead bacterial spores.

25. (Previously Presented) The method according to claim 1, wherein the size of the pores of the first filter are between about 2 µm and about 20 µm.

26. (Previously Presented) The method according to claim 1, wherein the size of the pores of the second filter are about 0.4 µm.

27. (Previously Presented) The method according to claim 1, wherein the contaminating microbes are aerobic or anaerobic bacteria, molds, yeasts, or live and/or dead

bacterial spores, and the size of the pores of the first filter are between about 2 μm and about 20 μm , and the size of the pores of the second filter are about 0.4 μm .

28.-36. (Cancelled)

37. (Previously Presented) The method according to claim 1, wherein the size of the pores of the first filter are about 11 μm or about 5 μm .

38. (Previously Presented) The method according to claim 1, wherein the contaminating microbes are aerobic or anaerobic bacteria, molds, yeasts, or live and/or dead bacterial spores, and the size of the pores of the first filter are about 11 μm or about 5 μm , and the size of the pores of the second filter are about 0.4 μm .

39. (New) The method according to claim 1, wherein the size of the pores of the second filter are about 0.3 to less than 1 μm .

40. (New) The method according to claim 1, wherein the contaminating microbes are aerobic or anaerobic bacteria, molds, yeasts, or live and/or dead bacterial spores, and the size of the pores of the first filter are between about 2 μm and about 20 μm , and the size of the pores of the second filter are about 0.3 to less than 1 μm .